



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,613	07/28/2006	Vipulkumar K. Patel	PB60707	8356
20462 7590 11/18/2008 SMITHKLINE BEECHAM CORPORATION CORPORATE INTELLECTUAL PROPERTY-US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939				
EXAMINER				
CHU, YONG LIANG				
ART UNIT		PAPER NUMBER		
1626				
NOTIFICATION DATE		DELIVERY MODE		
11/18/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary

Application No.

10/587,613

Applicant(s)

PATEL ET AL.

Examiner

YONG CHU

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 14-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 15-24 is/are rejected.
- 7) ☒ Claim(s) 2-9 and 14-24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1, 7, 14, and 19 are amended. Claim 24 is added. Claims 10-13 are canceled. Claims 1-9, and 14-24 are pending.

Response to Amendment

The amendment by Applicants' representative Dara L. Dinner dated on 08/22/2008 has been entered.

Response to Arguments/Remarks

Searched and examined subject matter

Applicants' argument that the Examiner should expand search and examination beyond the elected subject matter as described in the previous Office action has been fully considered, but is found not persuasive. The instant claim 1 encompasses various distinct subject matters. The searched and examined subject matter previously described encompasses the elected species and the preferred subject matter beyond the reasonable expanded search scope without serious burden to the Examiner, see MPEP§803.02 under Markush Claims. It is a reasonable scope of elected subject matter, and the claims were rejected. Per Applicants' request for further expanding search on the amended claims, search and examination are expanded to previously non-elected subject matter.

Specification

Applicants fail to amend the specification by adding continuing data to which the instant specification claims benefit from. Without this information, Applicants will lose

Art Unit: 1626

the claimed foreign priority because no ADS has been filed either. For interests of the Applicants, the objection is therefore maintained.

Rejection under 35 U.S.C. §112, 2nd paragraph

Applicant's amendments obviate the claim rejections.

Claim objection

Applicant's amendment of "B" into "B1" obviates the objection of Claim 1.

Applicants have overcome the claim rejections by the amendment, and the search and examination are expanded. Therefore, the objection for containing non-elected subject matter is moot.

Since the amendment has overcome the rejection, the Examiner has expanded the search to part of the previously non-elected subject matter, and new prior art renders the expanded scope of subject matter obvious as disclosed follow:

Claim Rejections - 35 USC § 103(a)

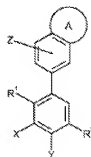
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

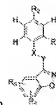
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 9, and 15-24 are rejected under 35 U.S.C. 103 (a) as unpatentable over the teachings by Thorarensen et al., *WO2004/018,428* ("the '428 publication") with PCT publication date 03/04/2004, and PCT filing date 08/22/2003, which claim benefit of U.S. provisional patent application Nos. 60/405429 on 08/23/2002 and 60/430,592 on 12/03/2002.

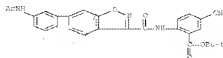


Applicants' claims relate to a compound of the Formula (I) according to claim 1, or a pharmaceutical composition comprising at least one compound thereof. The claimed compounds or compositions are useful in the treatment of conditions or diseases mediated by p38 kinase.

Determination of the scope and content of the prior art (MPEP §2141.01)



The '428 publication discloses a compound of the Formula with a



specific example (CAS RN 668970-25-0) for the treatment of conditions or diseases mediated by p38 kinase.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

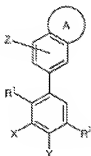
The difference between the '428 compound and the instantly claimed invention is that the substituents **Z** and **R¹** as -H vs. -methyl group (i.e. one of the claimed alkyl in **Z**), as being claimed in the instant claims.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

To those skilled in the medicinal chemistry art, the prior art teaching in the '428 publication renders the instantly claimed inventions obvious, because the difference between the prior art compound and a instantly claimed compound is the substituents **Z** and **R¹** as hydrogen vs. methyl on the phenyl ring. Both instant application and the prior art teach compounds used for the same pharmaceutical application for the treatment of conditions or diseases mediated by p38 kinase. For one ordinary skilled in the art, such difference is obviousness, In re Wood, 199 U.S.P.Q. 137 (C.C.P.A. 1978). Because knowing properties of one member of series compounds would in general know what to expect in adjacent members. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would

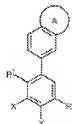
possess similar activity (i.e. pharmacological use). Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

Claims 1-9, and 15-24 are also rejected under 35 U.S.C. 103 (a) as unpatentable over the teachings by Angell et al., WO2004/010,995 ("the '995 publication") with PCT publication date 02/05/2004, and PCT filing date 07/30/2003. Applicants' claims relate

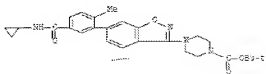


to a compound of the Formula (I) according to claim 1, or a pharmaceutical composition comprising at least one compound thereof. The claimed compounds or compositions are useful in the treatment of conditions or diseases mediated by p38 kinase.

Determination of the scope and content of the prior art (MPEP §2141.01)

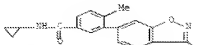


The '995 publication discloses a compound of the Formula according



to claim 1 with specific examples such as

(CAS



RN 651780-05-1) and (CAS RN 651780-60-8) for the treatment of conditions or diseases mediated by p38 kinase.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the '995 compounds and the instantly claimed invention is that the substituents **Z** as -H vs. -methyl group (i.e. one of the claimed alkyl in **Z**), as being claimed in the instant claims.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

To those skilled in the medicinal chemistry art, the prior art teaching in the '995 publication renders the instantly claimed inventions obvious, because the difference between the prior art compound and a instantly claimed compound is the substituents **Z** and **R¹** as hydrogen vs. methyl on the phenyl ring. Both instant application and the prior art teach compounds used for the same pharmaceutical application for the treatment of conditions or diseases mediated by p38 kinase. For one ordinary skilled in the art, such difference is obviousness, In re Wood, 199 U.S.P.Q. 137 (C.C.P.A. 1978). Because knowing properties of one member of series compounds would in general know what to expect in adjacent members. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (i.e. pharmacological use). Therefore, the instant claimed compounds would have been suggested to one skilled in the art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, and 15-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 11-12, and 15-26 of co-pending U.S. Patent application No. 10/522,955 ("the '955 application") with U.S. P&G publication . Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed scope between the instant claims 1-9, and 15-24 and claims 1-7, 11-12, and 15-26 of the '955 application are overlap, and the compounds (CAS RN 651780-05-1), and (CAS RN 651780-60-8) disclosed in the '955 application read on both claims. Therefore, instant claims 1-9, and 15-24 has been patented by claims 1-7, 11-12, and 15-26 of the ``955 application.

Claim Objection

Claims 2-9, and 14-24 are objected to depending on the rejected claim 1.

Conclusions

- Claims 2-9, and 15-24 are objected to.
- Claims 1-9, and 15-24 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. M²Kane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong Chu/
Patent Examiner
Art Unit 1626

/Kamal Saeed/
Primary Patent Examiner
Art Unit 1626